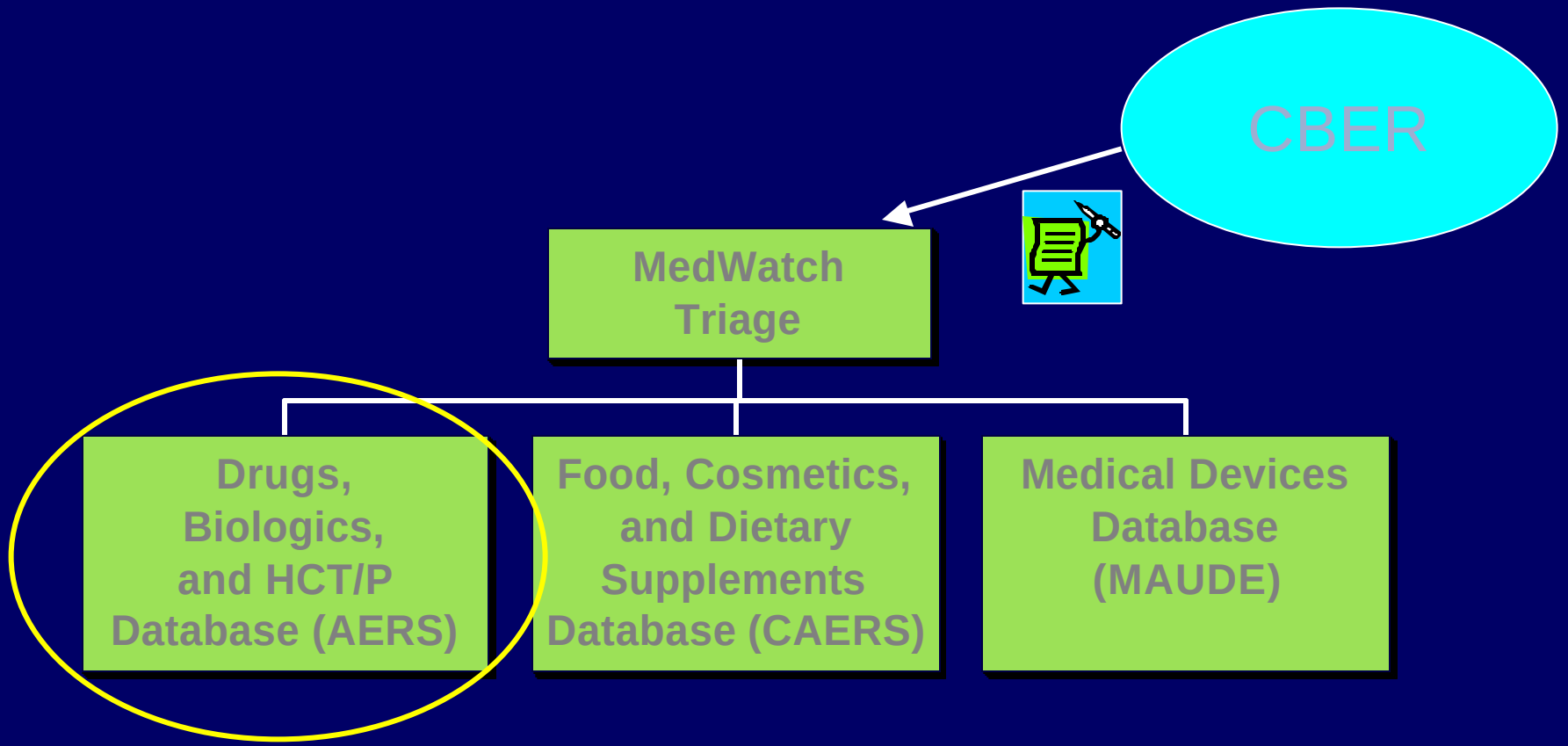
The Journey of an HCT/P MedWatch Report

Jacque Polder, BSN, MPH
Su Wang, MD MPH
FDA
Centers for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Epidemiology
Therapeutics and Blood Safety Branch

The Beginnings

- You send 2 copies of MedWatch report to CBER (HFM 210)
- CBER office keeps 1 and sends 1 to MedWatch
- MedWatch triages to appropriate database

The Journey: MedWatch Form Triage



MedWatch data entry: Where do the fields go?

A. Patient Information

B. Adverse Event and Product Problem

C*. Suspect medication- AERS or CAERS

D. Suspect Devices- ~~MAUDE~~

E. Initial Reporter

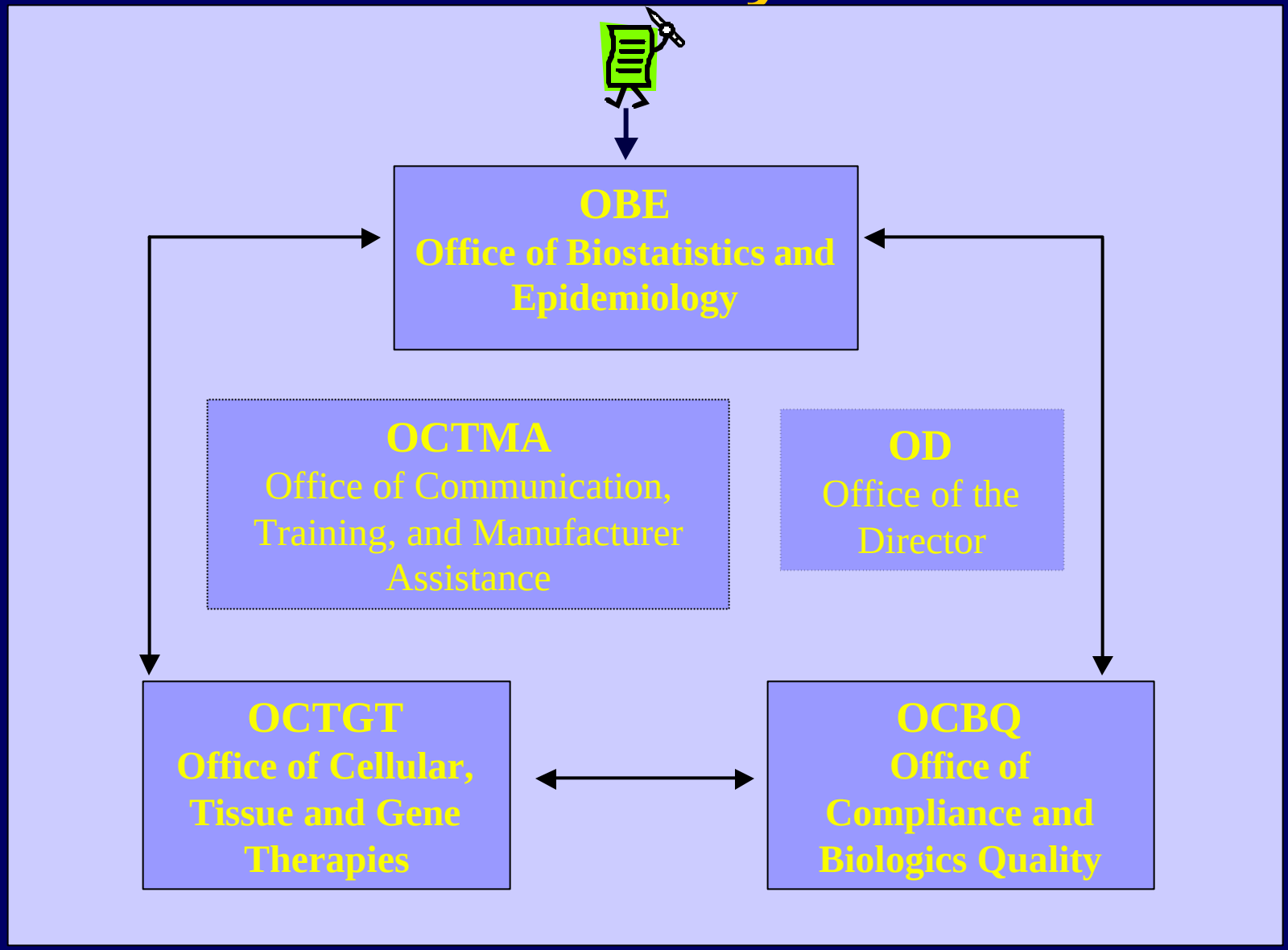
* With new MedWatch form, letters for fields will change and “Suspect Medication” will become “Suspect Product.”

While data entry is going on…..

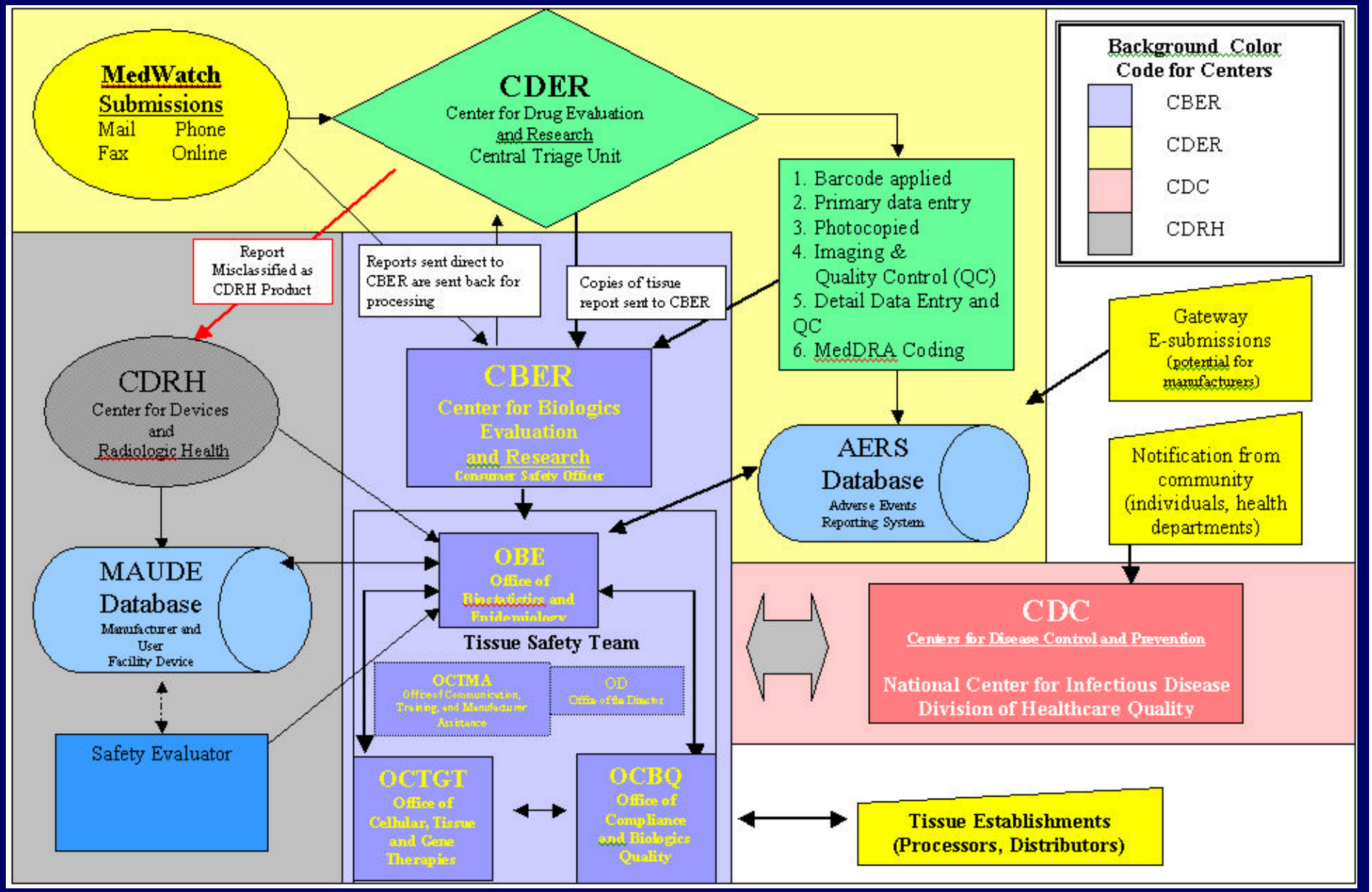
The MedWatch report travels through CBER

- We follow a Standard Operating Procedures and Policies (SOPP) for handling adverse reaction reports
- SOPP drawn up by Tissue Safety Team at CBER

Tissue Safety Team



HCT/P Safety at the FDA



Safety tasks at CBER

- Routine reviews of AERS database
- Analyses of reports
- Communicate with manufacturers
- Routine review of deviation database
- Quarterly review of cases
- Continued improvements of surveillance processes at the FDA

Overall mission: Working together for HCT/P safety